

IMPROVED EXPANDABLE GRAFT

The present application is a continuation-in-part of co-pending United States Patent Application Serial No. 09/273,736 filed March 22, 1999 entitled "Improved Expandable Graft" which in turn claims priority on provisional patent application Serial No. 60/081,824 filed April 15, 1998. The present application is also a continuation-in-part of co-pending United States Patent Application Serial No. 09/363,052 filed July 29, 1999 entitled "Coated Intraluminal Graft."

This invention relates to an improved expandable intraluminal graft for use within a body passageway, duct, blood vessel or other cavity and, more particularly, expandable intraluminal grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease.

BACKGROUND OF THE INVENTION

Heart disease is still one of the most prevalent medical ailments in the world. Intraluminal endovascular grafting, a type of angioplasty procedure, has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery and is used to treat heart disease. Intraluminal endovascular grafting involves a tubular prosthetic graft and delivery within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel. Almost 20 million angioplasty or related procedures involving occluded vasculature have been preformed worldwide. About 30% of these angioplasties fail within 30 days. These failures typically require the procedure to be repeated.

Several years ago, a product called a stent, named after Charles Stent, was introduced for use in angioplasty procedures. Hereinafter, the terms graft and stent are used interchangeably. The stent reduced the angioplasty failure rate to about 15 percent. A stent is an expandable metal tubular device that is mounted over an angioplasty balloon and deployed at the site of coronary narrowing. The balloon is inflated to expand the stent to physically open and return patency to the body passageway, duct or blood vessel. The balloon is then deflated and the stent is permanently disposed to retain the passageway, duct or blood vessel open. The first generation of expandable stents did not offer a controllable radial expansion. An improved stent is disclosed in United States Letters

Patent No. 4,733,665. The stent disclosed in the '665 patent overcame the problem associated with controlled expansion of the stent. However, prior art stents still do not provide control over the final, expanded configuration of the stent. For instance, the expansion of a particular coiled, spring-type stent is predetermined by the method of manufacturing, material and delivery system. In the case of self-expanding intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon exposure to core body temperature, the amount of expansion is predetermined by the heat expansion properties of the particular alloy utilized in the manufacture of the intraluminal graft. Consequently, once the foregoing types of intraluminal grafts were expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft could not be increased. If the diameter of the desired narrow lumened body passageway was not determined correctly, the graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. The stent disclosed in the '665 patent overcame the problems associated with these past stent designs.

The stent based upon the '665 patent is currently being used in angioplasty procedures. Stents, including the stent of the '665 patent, are presently used in approximately 30-60 percent of all angioplasty procedures. However, these stents have several short comings which contribute to the procedural failure rates. The currently used stents are not readily visible under fluoroscopic guidance procedures. Stent placement is hindered as a result of poor visibility. As a result, precise positioning of the stent during the insertion procedure was difficult to achieve. Consequently, the stent could be inadvertently positioned in the wrong or non-optimal location. These stents also shorten longitudinally after radial expansion, which is not desirable for their intended use. The shortening of the stent resulted in longitudinal movement of the stent during expansion which sometimes resulted in the stent being fully expanded in the wrong or non-optimal position.

The improved stent disclosed in United States Patent Application Serial No. 09/273,736 filed March 22, 1999, which is incorporated herein by reference, overcomes these past problems with stents. The patent application discloses an improved stent that can be coated with one substance in various regions to improve the visibility of the stent by various techniques (e.g. fluoroscopy) during

the insertion procedure thereby improving the positional accuracy of the stent in a body cavity. The improved stent also incorporates a unique design which enables the stent to retain its original longitudinal length during expansion of the stent.

5 Although the improved stent overcomes the deficiencies of prior art stents with respect to accurate stent positioning, problems still exist with respect to tissue damage by the stent during insertion and/or expansion of the stent. The two ends of prior art include one or more rough, sharp or pointed surfaces. These surfaces can cause irritation and/or damage to surrounding tissue as the stent is moved within the body cavities. Such irritation or damage to the surrounding tissue can create various types of complications during the surgical procedure. These surfaces can also cause damage to surrounding tissue during the expansion of the stent. During stent expansion, the middle 10 of the stent is first expanded by the angioplasty balloon. As the middle of the stent expands, the ends of the stent move toward one another. This movement of the ends can result in the stent ends digging into and/or penetrating the surrounding tissue. Further, tissue damage can result when the end portions of the stent are eventually expanded by the balloon.

15 Several problems can develop after the stent is inserted into a passageway. One problem is known as in-stent restenosis wherein the passageway, which has been previously treated with a stent, renarrows or closes within the stented segment. The renarrowing or closure of the passageway can be caused by a structural failure of the stent due to contractive forces by the passageway on the stent and/or by the passageway growing into the openings in the stent. Other problems can include 20 vascular narrowing and restenosis. Vascular narrowing is defined as a vascular segment that has not been previously treated by any interventional means and eventually closes preventing blood flow. Restenosis is the renarrowing of a previously treated vascular segment not involving a stent. Both of these problems are the result of a passageway that was not treated with an invasive angioplasty, narrowing or closing. Both of the problems result from the insertion of a stent in one portion of the 25 passageway causing vascular narrowing or restenosis in another part of the passageway. Vascular narrowing, restenosis and in-stent restenosis are caused by biological factors causing the premature closing of vessels. One such agent is platelet derived growth factors, referred to as PDGF. PDGF

is an intercellular messenger capable of stimulating proliferation of smooth muscle cells. Smooth muscle cells migrate within the artery and cause a restenotic reaction. The problems with vascular narrowing, restenosis and in-stent restenosis are significantly overcome by the inclusion of a drug coated on the stent disclosed in co-pending United States Patent Application Serial No. 09/363,052 filed July 29, 1999 entitled "Coated Intraluminal Graft," which is incorporated herein by reference. The '052 patent application discloses that at least a portion of the graft is coated with a substance which inhibits the occurrence of in-stent restenosis, vascular narrowing and/or restenosis.

In view of the present stent technology, there is a need and demand for a stent that has improved procedural success rates, has higher viability under fluoroscopy *in vivo*, retains its longitudinal dimensions from its original pre-expanded configuration to the expanded state, and minimizes damage to tissue during the insertion and expansion of the stent.

SUMMARY OF THE INVENTION

This invention pertains to an improved expandable intraluminal graft designed to meet the present day needs and demands relating to intraluminal grafts. The present invention includes a member having first and second ends and a wall surface disposed between the first and second ends. The wall surface is typically formed by a plurality of intersecting elongated members, and at least some of the elongated members typically intersect with one another at a point intermediate to the first and second ends of the member. The member has a first cross-sectional area which permits intraluminal delivery of the member into a body passageway having a lumen, and a second, expanded cross-sectional area. The expansion of the member can be accomplished in a variety of manners. Typically, the member is expanded to its second cross-sectional area by a radially, outwardly extending force applied at least partially from the interior of the member. The second cross-sectional area is variable and dependent upon the amount of radially outward force applied to the member. Typically, the member is expanded to expand the lumen of the body passageway while retaining its original length. Typically, the first cross-sectional shape of the graft is substantially uniformly circular to form a substantially tubular graft; however, the graft can have other cross-sectional shapes such as, but not limited to, oval, elliptical, polygonal, and the like.

Another and/or alternative feature of the present invention is that the plurality of elongated members are a plurality of wires, and the wires are secured to one another where the wires intersect with one another. In one specific embodiment, the tubular member is at least partially made of a wire mesh tube. The wire mesh tube may be utilized as the intraluminal graft. The wire mesh tube can be radially expanded to a second diameter within the body passageway; the second expanded diameter being variable and determined by the desired expanded internal diameter of the body passageway, duct, blood vessel, etc., whereby the expanded wire mesh tube will not migrate from the desired location within the body passageway, duct, blood vessel, etc., and the expansion of the intraluminal graft does not cause a rupture of the body passageway, duct, blood vessel, etc.

Yet another and/or alternative feature of the present invention is that the plurality of elongated members include a plurality of thin bars secured to one another where the bars intersect with one another.

Still yet another and/or alternative feature of the present invention is that the elongated members form at least one parallelogram which, upon expansion, retains the original longitudinal length of the graft.

Another and/or alternative feature of the present invention is that the graft includes at least one set of slots arranged with respect to one another to maintain the original longitudinal length of the graft when the graft is expanded.

Yet another and/or alternative feature of the present invention is that the graft is formed by an etching process and/or by laser cutting.

Still another and/or alternative feature of the present invention is that the member has a biologically inert coating on its wall surface. The coating can be used to reduce infection, irritation and/or rejection of the graft.

Still yet another and/or alternative feature of the present invention is that the graft, upon expansion, substantially maintains its original longitudinal length.

Another and/or alternative feature of the present invention is that the graft includes at least two members that are connected together by at least one connector that allows transverse bending

and flexibility invariant to the plane of bending.

Still another and/or alternative feature of the present invention is that the connector is a generally "U" shaped connector.

Yet another and/or alternative feature of the present invention is that the member is made of and/or includes a material that is more visible under fluoroscopy in vivo than currently available stents. The member can include a special material such as, but not limited to, gold to enhance the visibility of the member in a body passageway, duct, blood vessel, etc.

Still yet another and/or alternative feature of the present invention is the material to make the member visible under fluoroscopy. Typically, this is accomplished by adhering, mounting, welding or braising a second material to at least a portion of the outer surface of the member to enhance the visibility of the member. In one aspect of the embodiment, the second material is secured to the member so as to only come in contact with the inner luminal surface of the vessel and not any blood borne components that could accelerate stent failure rates. In one specific embodiment, the second material is at least partially located at at least one end, and typically both ends, of the tubular member. This positioning of the material on the stent helps to identify the location of the ends of the stent, thus enhancing the critical placement of the stent so as to reduce the failure rate. In another specific embodiment, the second material is at least partially located on the outer surface of the tubular member at the connecting flexible joints of the tubular member. This location of the second material also enhances the critical placement of the stent around areas of high tortuosity so as to reduce the failure rate.

Another and/or alternative feature of the present invention is the material used to make the member visible under fluoroscopy located on the outer surface of the member located at both ends of the member. This location shows where the member both begins and ends in the body cavity thus enhancing the critical placement of the graft so as not to accelerate the failure rate.

Yet another and/or alternative feature of the present invention is the material used to make the member visible under fluoroscopy is located on the outer surface of the tubular member at the connecting flexible joints of the member at any position between the two ends. This also enhances

the critical placement of the graft around areas of high tortuosity so as not to accelerate the failure rate.

Still another and/or alternative feature of the present invention is the graft material is treated with Gamma or Beta radiation to reduce the vascular narrowing of the stented section. The radioactive treatment inactivates the cell migration and properties thereof within a 3 mm depth of the arterial wall.

Still yet another and/or alternative feature of the present invention is that a wire mesh tube is utilized as the intraluminal graft. The wire mesh tube is radially expanded to a second cross-sectional area within the body passageway; the second, expanded cross-section being variable and determined by the desired expanded internal diameter of the body passageway, duct, blood vessel, etc, whereby the expanded wire mesh tube will not migrate from the desired location within the body passageway, duct, blood vessel, etc., and the expansion of the intraluminal graft does not cause a rupture of the body passageway, duct, blood vessel, etc.

Another and/or alternative feature of the present invention is that the intraluminal graft can be inserted and expanded by standard procedures. Therefore, the intraluminal graft can be inserted into a body passageway, duct, blood vessel, etc., until it is disposed at the desired location within the body passageway. The intraluminal graft is radially expanded outwardly into contact with the body passageway until the lumen of the body passageway at the desired location, luminal narrowing, has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing.

A further and/or alternative feature of the present invention is that the graft is at least partially coated with a substance that inhibits and/or reduces restenosis, vascular narrowing and/or in-stent restenosis.

Yet another and/or alternative feature of the present invention is that a substance is at least partially coated onto the graft to inhibit PDGF activity in the passageway. After a stent is inserted into a passageway, the stent may induce some irritation in the passageway. The biological factor, PDGF, is turned on due to such irritation and activates the components of clotting. These components can cause clotting in the stent area or in adjacent areas. This clotting can cause the

passageway to narrow or ultimately close. The substance coated on the stent is formulated to deactivate and/or inhibit the activity of the PDGF, thereby reducing the occurrence of in-stent restenosis, vascular narrowing and/or restenosis.

Still yet another and/or alternative feature of the present invention is that the PDGF inhibitor includes triazolopyrimidime (Trapidil). A damaged endothelium exposes the connective tissue to platelet aggregation and to local release of PDGF. Numerous animal models have shown that platelet adhesion to the vascular wall of this damaged endothelium soon triggers the proliferation and migration of smooth muscle cells. If platelets are a source of PDGF, it has now been demonstrated that endothelial cells, macrophages and smooth muscle cells are also a source of PDGF following vascular trauma. The influence of Trapidil on platelet aggregation is linked to inhibition of the synthesis of thromboxane A2 and the partial blocking of thromboxane A2 receptors. Trapidil is able to normalize an incorrect balance between thromboxane A2 and prostacycline. Thromboxane A2 is a powerful inducer of platelet aggregation. It is also responsible for the contraction of smooth muscles of vessels and stimulates the proliferation of the arterial intimal cells. Prostacyclin inhibits platelet aggregation and vasodilator properties. Trapidil also has antithrombotic properties. It can significantly reduce thrombosis induced by creation of an arteriovenous conduit, as compared to aspirin and dipyridamole, which only had a modest affect. Trapidil has other desirable properties such as vasodilation, a decrease in angina and an increase in HDL levels in patients with ischemic heart disease. Trapidil, at present, represents the most fully documented agent demonstrating a pharmacological and clinical effect in inhibition of restenosis. Prior substances have been coated onto stents to address one or more problems associated with the use of stents. These substances include heparin, colchicine and dexamethazone, among others. These substances are used to inactivate platelets, stop cell division and prevent cell adhesion. The problems associated with the use of these substances have varied effects. Heparin is not potent enough to extend a clinical effect. Colchicine has been shown to kill the cells in the surrounding area and actually propagate the problem. And dexamethazone has not provided the desired restenosis prevention. However, as can be appreciated, aspirin, colchicine, dexamethazone dipyridamols, heparin and/or derivatives thereof

can be substituted for, or used in combination with, Trapidil on the stent. Trapidil has a affinity to exert clinical effects starting in the second hour of treatment. This inhibition of platelet aggregation is reflected in a significant increase in collagen and ADP. The platelet inhibition in the first day of treatment with Trapidil continues through the thirtieth day. The philosophy of a multifactoral approach, including but not limited to the increasing success of angioplasty and stent associated with a considerable reduction in complications, has been the reason behind the use of this technique in a large scale in the treatment of patients with coronary heart disease. Restenosis is the most important limitation to the long term benefits of angioplasty and a stent combination. A pharmacological approach aiming to intervene in the mechanism of restenosis will be needed to supplement the mechanical approach of the revascularization procedure. Various approaches have been proposed for the prevention of restenosis. To use a novel drug such as Trapidil delivered as a coating on a stent locally to the affected area hereby corresponds to this approach.

Yet another and/or alternative feature of this invention corresponds to the local delivery of the substance to inhibit and/or prevent restenosis, vascular narrowing and/or in-stent restenosis, such as Trapidil, through an angioplasty balloon with the physical capability to transfer solute of the substance through the balloon membrane to the affected sight. This delivery can be in the form of a stream, a slow oozing delivery or a bolus injection. The delivery can be made through magnetic, electrical or physical means. The delivery is accomplished through a separate lumen capable of channeling the solute of the substance to the affected area. This delivery through a balloon also delivers the substance to the sight of restenosis, vascular narrowing and/or in-stent restenosis.

Another and/or alternative feature of the present invention is that the substance to inhibit and/or reduce restenosis, vascular narrowing and/or in-stent restenosis may be partially coated on specific regions of the stent or may be totally coated on the stent. The thickness of the coating is not as important as the concentration of the substance needed to acquire the desired affect.

Still another and/or alternative feature of the present invention is the substance to inhibit and/or reduce restenosis, vascular narrowing and/or in-stent restenosis is coated onto the stent by the use of an intermediate compound. Typically, the compound is a synthetic or biocompatible material

that does not adversely affect the substance or cause problems or adverse reactions in the passageway.

A further and/or alternative feature of the present invention is a graft that includes rounded, smooth and/or blunt end surfaces that minimize and/or prevent damage to body cavities as the graft is inserted into a body cavity and/or expanded in a body cavity. The modified end surfaces are designed to reduce the cutting and/or piercing of tissue as the graft is positioned in a body cavity. Typically, the path from the point of entry into a body cavity and the final position of the graft in the body cavity is not straight. As a result, the graft is caused to be weaved through the body cavity to reach the final position in the body cavity. This weaving of the graft can result in the front and/or back ends of the graft to cut, scrape or otherwise damage tissue in the body cavity as the graft is moved in the body cavity. The rounding, smoothing and/or blunting of the end surfaces significantly reduces possible damage to the tissue. Damage to the tissue in the body cavity can also occur during the expansion of the graft. The rounding, smoothing and/or blunting of the end surfaces likewise significantly reduces possible damage to the tissue during the expansion of the graft.

In summary, the present invention includes a radially expandable, prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongated members and is designed to reduce stent failure and/or narrowing or closure of a non-treated portion of the passageway and reduce damage to the tissue of the body cavity.

These and other advantages will become apparent to those skilled in the art upon the reading and following of this description taken together with the accompanied drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference may now be made to the drawings, which illustrate various embodiments that the invention may take in physical form and in certain parts and arrangements of parts wherein:

FIGURE 1 is a perspective view of an expandable intraluminal graft which permits delivery of the graft, or prosthesis, into a body passageway;

FIGURE 1A is an enlarged perspective view of one end of the graft of FIGURE 1;

FIGURE 2 is a perspective view of the graft of FIGURE 1 in a non-tubular state;

FIGURE 3 is a sectional view of the graft of FIGURE 2 showing a connector used to connect the ends of two tubular sections of the graft;

5 FIGURE 4 is a sectional view of the graft of FIGURE 2 showing the parallelogram structure of the graft before and after expansion;

FIGURE 5 is a perspective view of an additional embodiment of the present invention;

10 FIGURE 6 is a sectional view of the graft of FIGURE 5 showing a connection used to connect the ends of two sections of the graft together;

FIGURE 7 is a sectional view of the graft of FIGURE 5 showing the location and angular orientation of opening in the graft;

15 FIGURE 8 is a sectional view of the graft of FIGURE 5 showing a part of the structure of the graft before and after expansion;

FIGURE 9 is a perspective view of an intraluminal graft of FIGURE 1 showing a coating of a substance on the graft; and

20 FIGURE 10 is a perspective view of an angioplasty balloon delivering fluid materials to a local site.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings wherein the showing is for the purpose of illustrating preferred embodiments of the invention only and not for the purpose of limiting the same, FIGURES 20 1-9 disclose an intraluminal graft, such as an expandable prosthesis, for a body passageway. It should be understood that the terms "expandable intraluminal graft," "expandable prosthesis" and "stent" are interchangeably used to some extent in describing the present invention. The apparatus and structures of the present invention may be utilized not only in connection with an expandable intraluminal graft for expanding partially occluded segments of a blood vessel or body passageway, but also for additional uses. For example, the expandable prostheses may be used for, but not limited to, such purposes as 1) a supportive graft placement within a blocked vasculature opened by transluminal recanalization, which are likely to collapse in the absence of an internal support; 2)

forming a catheter passage through mediastinal and/or other veins occluded by inoperable cancers; 3) reinforcement of catheter created intrahepatic communications between portal and/or hepatic veins in patients suffering from portal hypertension; 4) supportive graft placement of narrowing of the esophagus, the intestine, the ureter and/or the urethra; 5) and supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, and/or blood vessel within the human vascular system.

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The expandable intraluminal graft, as shown in FIGURES 1, 2, 3, and 4, generally comprises a tubular shaped member 20 having a first end 30, a second end (not shown) and a wall surface 50 disposed between the first and second ends. Typically, the wall surface is formed by a plurality of intersecting elongated members 60 with at least some of the elongated members intersecting with one another intermediate the first and second ends of the tubular shaped member. The tubular shaped member has a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen. FIGURE 1 shows a perspective view of a section of the tubular shaped member 20 which has a second, expanded diameter, which second diameter is variable in size.

20 Elongated members 60, which form the wall surface of the tubular shaped member can be any suitable material which is compatible with the human body and the bodily fluids with which the graft, or prosthesis, may come into contact. Typically, the elongated members made of a material include and/or are coated with a material readily visible in vivo under fluoroscopic view. The elongated members also are made of a material which has the requisite strength and elasticity characteristics to permit the tubular shaped member to be expanded from its original tubular form to its expanded tubular form and to further permit the tubular shaped member to retain its expanded configuration with the enlarged diameter. Suitable materials for the fabrication of the tubular

shaped structure include tantalum, stainless steel, titanium, or any suitable plastic material having the requisite characteristics previously described. Typically, the tubular shaped structure is made of stainless steel.

Elongated members 60 are generally small diametered wires or bars that have a maximum cross-sectional length or diameter of up to about 0.02 inches, and typically about 0.0005 to 0.008 inches. It should, of course, be understood that each elongated member can have a variety of different cross-sectional configurations along part, or the complete length of, each member. Such configurations include circular, oval, diamond, triangular, square, rectangular, hexagonal, etc.

A plurality of elongated members can be connected together to form the tubular member. To provide flexibility to the tubular member, the elongated members are connected together by a connector. One such connector is a "U" shaped member 70 where the elongated members 60 join with one another as shown in FIGURES 1-3.

Referring now to FIGURE 1A, end section 30 includes a plurality of ends 40. The ends are formed, filed, buffed, and the like so as to have generally smooth surfaces. As a result, sharp edges, pointed surfaces and the like are substantially eliminated from the end section. Typically both ends of the tubular member include ends having smooth surfaces. The smooth surfaces of the ends reduce damage to surrounding tissue as the tubular member is positioned and expanded in a body cavity. In addition to ends 40 having generally smooth surfaces, the elongated members 60 and/or joints between the elongated members are formed, filed, buffed, and the like to also have generally smooth surfaces. The substantial removal of sharp edges, pointed surfaces and the like from the entire tubular member and connectors reduces damage to surrounding tissue as the tubular member is positioned and expanded in a body cavity.

The elongated members can be formed by a variety of processes. Typically, the elongated members are formed by etching a single, tubular piece of material so that each individual intersections of the elongated members need not be welded. For example, a tubular shaped member is initially formed from a thin-walled metal tube, and the openings between the intersecting bars are formed by a conventional etching process, such as electromechanical or laser etching, whereby the

resultant structure is a tubular shaped member having a plurality of intersecting elongated members as shown in FIGURES 1 and 2. This technique enhances the structural integrity of the tubular structure and reduces the number of rough surfaces at the intersection points.

One particular design of the pattern of the tubular members is shown in FIGURES 1 and 2.

5 The openings between the intersecting bars are generally parallelogram in shape. The openings are positioned to form a pattern as shown in FIGURE 4. As can be appreciated, this parallelogram pattern allows the tubular shaped members to be expanded without the members having a reduction in length in the longitudinal direction. Since a parallelogram is a four sided figure with opposite sides being parallel, the longitudinal axis of structure of member 60 will remain the same as the sides are elongated and as the angle of the parallelogram changes during expansion. Typically, the surface 10 of the tubular member is formed by a plurality of parallelograms.

15 As shown in FIGURE 1, the arrangement for connecting two tubular members 60 together is by at least one "U" shaped member 70 to increase the flexibility of the graft. The connector is shown to be a "U" shaped member 70 that connects two ends of the tubular members 60 together. As shown in FIGURES 1-3, a plurality of "U" shaped members 70 are used to connect a set of two adjacently positioned ends of one tubular member to a corresponding set of adjacently positioned ends in the other tubular member. This configuration allows at least two tubular members that are 20 connected together by at least one set of circularly distributed "U" shaped connector to transverse, bend and improve flexibility invariant to the plane of bending. As can be appreciated, other shaped connectors which include an arcuate portion can be used.

25 Referring now to FIGURES 2 and 3, the size of the "U" shaped connector is a function of the size and spacing of the elongated members. The length of the "U" shaped member is typically about the sum of twice the thickness of the wire or bars of the elongated members plus the height of the parallelogram in the non-expanded shape ($2a + b$). The spacing of a non-connected end of an elongated member from the "U" shaped member when the tubular shaped member 20 is in a non-expanded position is about equal to the thickness of the elongated member. The spacing and configuration enables the desired flexibility of the tubular member and proper expansion of the

tubular member.

Referring now to FIGURES 5, 6, 7, and 8, a second embodiment of the present invention is illustrated. As shown in FIGURE 5, a graft 100 includes two sections 110, 112. However, graft 100 may include more than two sections. The two sections 110, 112 are connected together by 5 connectors 120. Generally, connector 120 is arcuate in shape, and typically is "U" shaped. As shown in FIGURE 5, sections 110, 112 are substantially symmetrical to one another and typically have substantially identical dimensions. Each section includes a plurality of slots 130, 132. Slots 130, 132 are typically equal in length and width. Each series of slots 130 are arranged substantially parallel to one another. Each series of slots 132 are also arranged substantially parallel to one another. Slots 130 and 132 are positioned relative to one another to form an angle between 0-90° 10 when the graft is in the unexpanded position as shown in FIGURE 5. The slot arrangement between ends 140 and 142 of graft 100 allow the graft, when expanded radially, to retain its original pre-expanded length. The configuration of the slots 130, 132 in the pre-expanded and post-expanded 15 position is shown in FIGURE 8. The slots can be formed in a variety of manners. Typically, the slots are formed by laser cutting. The formation of slots 130, 132 by use of a laser is shown in FIGURE 7. The configuration of connectors 120 is shown in FIGURE 6. As shown in FIGURES 5 and 6, connectors 120 are secured to an extension bar 150 and to end 146 of the second section 112 or to end 144 of the first section 110. Extension bar 150 alternates connection between end 144 of 20 the first section 110 and end 146 of the second section 112.

Referring now to FIGURE 9, a tubular member 200 is shown to include a compound 210 on the elongated members 220 and connector 230 of the tubular member. Compound 210 is a substance that inhibits and/or prevents restenosis, vascular narrowing and/or in-stent restenosis. One preferable compound is a PDGF inhibitor such as Trapidil.

As can be appreciated, the amount of PDGF inhibitor delivered to a certain region of a 25 passageway can be controlled by varying the coating thickness, drug concentration of the PDGF inhibitor, and/or the amount of surface area of the tubular member 200 is coated with the PDGF inhibitor. As can also be appreciated, the PDGF inhibitor can be combined with, or at least partially

coated with a substance that affects the rate to which the PDGF inhibitor is released from the surface of the stent. A bonding compound can be used in conjunction with compound 210 to assist in binding compound 210 to tubular member 200. In addition, or alternatively, the bonding compound can be used to control the release of compound 210 into the body passageways. In one particular 5 application, the bonding compound is biodegradable and dissolves over the course of time. The bonding agent is coated at one or more thicknesses over compound 210 to delay delivery of compound 210 into a body passageway.

Referring now to FIGURE 10, compound 210 is delivered into a body passageway A via balloon 250. Balloon 250 includes one or more slots 260 to allow delivery of compound 210 into body passageway A. Balloon 250 can be used to both deliver compound 210 and expand tubular member 200, or be used in conjunction with another balloon or tubular member expanding device. Due to the properties of the PDGF inhibitor, local delivery of the inhibitor by a stent is highly advantageous.

The present invention has been described with reference to a number of different embodiments. It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. It is believed that many modifications and alterations to the embodiments disclosed will readily suggest themselves to those skilled in the art upon reading and understanding the detailed description of the invention. It is intended to include all such modifications and alterations insofar as they come within the scope of 10 15 20 the present invention.